IN THE MATTER OF \* BEFORE THE

UNIVERSITY OF MARYLAND \* MARYLAND

BALTIMORE WASHINGTON \* HEALTH CARE

MEDICAL CENTER \* COMMISSION

Docket No.: 19-02-CP016 \*

# STAFF REPORT AND RECOMMENDATION

# CERTIFICATE OF ONGOING PERFORMANCE FOR PRIMARY & ELECTIVE PERCUTANEOUS CORONARY INTERVENTION SERVICES

July 16, 2020

#### I. INTRODUCTION

# A. Background

Percutaneous coronary intervention (PCI), commonly known as coronary angioplasty, is a non-surgical procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing. Primary (or emergency) PCI programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Elective (or non-primary) PCI programs provide interventions that revascularize coronary arteries that are substantially blocked but have not yet resulted in an immediate cardiac event.

For many years, only Maryland hospitals with on-site cardiac surgery services could provide PCI. However, in the 1990s, Maryland began allowing some hospitals to perform primary PCI services without cardiac surgery on-site, first as part of research trials evaluating the safety of providing primary PCI at such hospitals and, later, as a regular clinical service, based on the research findings. The Commission issued waivers to the co-location requirement. In the following decade, similar research evaluated the safety of providing elective PCI services at hospitals without on-site cardiac surgery.

The nine Maryland hospitals that obtained waivers to provide elective PCI services participated in a multi-site clinical trial, C-PORT E, a study that was approved by the Commission upon the recommendation of its Research Proposal Review Committee. This non-inferiority study provided evidence that elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. In 2012, the Maryland legislature passed a law directing the Commission to establish a process and minimum standards for a hospital to obtain and maintain Certificates of Ongoing Performance for the provision of cardiac surgery and PCI. The legislation required the Commission to establish a Clinical Advisory Group (CAG) to advise the agency on development of regulations to implement the new law.

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac Surgery Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Surgery Chapter was subsequently revised in November 2015 and again in January 2019. The main change in these revisions to the Cardiac Surgery Chapter that affects PCI programs has been a change to the benchmark used to evaluate hospitals' risk-adjusted mortality rates. Commission staff was unable to obtain benchmark information for risk-adjusted mortality rates consistent with the regulations adopted in November 2015 that reflected the recommendations of the CAG. As a result, the standard addressed by applicants was determined to be inapplicable; however, information on how hospitals performed relative to the newly adopted mortality standard is included in staff reports.

The Cardiac Surgery Chapter contains standards for evaluating the performance of established PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and

elective (nonprimary) PCI services, for a period specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

# **B.** Applicant

#### **University of Maryland Baltimore Washington Medical Center**

The University of Maryland Baltimore Washington Medical Center (BWMC) is a 285-bed general hospital located in Glen Bernie (Anne Arundel County). BWMC is part of the University of Maryland Medical System and does not have a cardiac surgery program on site.

BWMC began providing primary PCI services in February 2001 under a research waiver as a participating hospital in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials. In 2006, BWMC was among the first group of non-cardiac surgery hospitals authorized to provide primary PCI on a regular basis subject to ongoing performance requirements and periodic waiver renewal. In 2009, the Commission granted a two-year research waiver to BWMC and BWMC began performing elective PCI in 2009 through its participation in the Atlantic Cardiovascular Patient Outcomes Research Team: Elective Angioplasty Study (C-PORT E) multi-center research study; the study concluded subject enrollment on March 21, 2011. BWMC filed an application to seek the continuation of these waivers through participation in a follow-on elective PCI registry until the Commission considered the published results of the study and made appropriate changes to the State Health Plan Chapter. Currently, BWMC provides primary and elective PCI services.

#### **Health Planning Region**

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. JHBMC is in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties and Baltimore City. Fourteen hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; all the other programs provide both primary and elective PCI services. Five of the fourteen hospitals also provide cardiac surgery services, and one additional hospital in this region has a Certificate of Need to establish a cardiac surgery program.

#### C. Staff Recommendation

MHCC staff recommends that the Commission approve BWMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. A description of BWMC's documentation of its performance and MHCC staff's analysis of this information follows.

#### II. PRODEDURAL HISTORY

BWMC filed a Certificate of Ongoing Performance application on March 22, 2019, in accordance with the review schedule determined by the Commission. MHCC staff reviewed the application and requested additional information on January 27, 2020, March 20, 2020, June 12, 2020, and June 29, 2020. Additional information was submitted on February 20, 2020, April 9, 2020, June, 23, 2020, June 26, 2020, and June 30, 2020.

#### III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

# **Data Collection**

10.24.17.07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

BWMC stated that it participates in multiple data registries of the American College of Cardiology (ACC), including the NCDR CathPCI, ICD, and ACTION registries. BWMC also participates in the American Heart Association's Get With the Guidelines (GWTG) registry for patients with coronary artery disease.

#### **Staff Analysis and Conclusion**

BWMC has complied with the submission of ACC-NCDR CathPCI data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR CathPCI data to validate that hospitals submitted accurate and complete information. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of BWMC's data reported during the audit period.

MHCC staff concludes that BWMC complies with this standard.

# **Institutional Resources**

10.24.17.07D(4)(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction 24 hours per day, seven days per week.

BWMC provided all cardiac catheterization laboratory (CCL) closures since January 2015 and additional information about the reasons for closure, as shown in Table 1.

**Table 1: BWMC CCL Downtime** 

Date	Duration of Closure (hours)*	Reason/Explanation
1/6/15-1/7/15	13.5	No available transport service
2/21/15-2/22/15	24.0	No available transport service
8/3/15	6.5	Interventional cardiologist ill
1/15/16	13.5	Death of CCL staff member
1/21/16	5.0	Funeral for CCL staff member
5/17/16	0.75	Air conditioning not working in CCL
8/15/16-8/16/16	9.5	Sewage backup in CCL from ICU
5/7/18	1.0	Air handler malfunction
6/27/18	3.0	OR breaker downtime – all data services down
6/7/19	2.75	Collimater malfunction/repair
6/8/19	2.5	Collimater malfunction/repair
12/11/19-12/12/19	33.5	Failed compressor

Source: BWMC Application, Updated Q2

BWMC provided information documenting rare and unforeseen closures. Specifically, no available transport service, death/funeral or illness of a staff member, air conditioning, air handler, or compressor malfunction, sewage backup, breaker downtime (i.e. all data services in facility were down), and collimater malfunction/repair. In addition, BWMC reported four instances where the facility was already functioning at capacity and was unable to take on another primary PCI case because of cases in progress. These cases occurred three times in 2015 and once in 2019.

In another case, for a STEMI patient, who arrived on June 27, 2018, the patient was transported to the University of Maryland Medical Center (UMMC) because the CCL was unavailable. This patient self-presented shortly after the downtime started and after Maryland Institute for Emergency Medical Services Systems (MIEMSS) was notified that the CCL was not available.

BWMC explained that it has only one call team during nights and weekends. During regular business hours, the CCL can accommodate up to two cases simultaneously. However, after hours, the CCL can only accommodate one case at a time.

BWMC provided information about its process for redirecting patients. The CCL notifies the Emergency Department (ED) Charge Nurse, who then notifies the Emergency Medical Resource Center and ED leadership. ED leadership notifies the Administrator on call, and EMS redirects STEMI patients, whenever possible, to a facility with percutaneous coronary intervention services. Patients who self-present can be administered thrombolytics and transferred, as necessary. When PCI services are unavailable, MIEMMS is notified, in advance if possible, and cases are diverted.

# **Staff Analysis and Conclusion**

BWMC's CCL was unable to accommodate patients a total of 16 times between January 2015 and December 2019, due to equipment malfunction or unforeseen circumstances. MHCC staff reviewed the reported downtime for the CCL from January 2015 through December 2019 and requested additional clarification. In cases when the CCL was unavailable, BWMC provided reasons for closure that generally reflect unforeseeable issues or reasonable judgment by the hospital.

BWMC provided a log of CCL maintenance and repairs for the period December 2013 through October 2019. This log indicates that there were no instances where both CCL rooms were closed due to routine maintenance or repairs. BWMC also submitted service logs for Toshiba and GE CCL Equipment that describe necessary maintenance and repairs in greater detail.

MHCC staff concludes that BWMC complies with this standard.

10.24.17.07D(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

BWMC provided a signed statement from Karen E. Olscamp, President and Chief Executive Officer, acknowledging that BWMC is committed to providing timely primary PCI services, as required by this standard. As shown in Table 2, BWMC also provided quarterly information on the percentage of non-transfer STEMI patients who received primary PCI within 90 minutes and median door-to-balloon (DTB) times for STEMI patients who were treated at BWMC between January 2015 and June 2019.

BWMC reported that the hospital did not receive any transfer patients who required primary PCI.

Table 2: BWMC Reported Compliance with DTB Time Benchmark for Primary PCI Cases

	Non-Transfer Cases				
Quarter	Percent of Cases With DTB <=90 Minutes	Median DTB			
CY2015 Q1	93.8	56.6			
CY2015 Q2	96.2	52.5			
CY2015 Q3	96.6	51.0			
CY2015 Q4	93.3	46.0			
CY2016 Q1	95.0	52.5			
CY2016 Q2	100.0	62.0			
CY2016 Q3	91.0	63.0			
CY2016 Q4	96.0	64.0			
CY2017 Q1	100.0	66.0			
CY2017 Q2	100.0	53.0			
CY2017 Q3	95.8	53.0			
CY2017 Q4	90.0	62.0			
CY2018 Q1	100.0	60.0			
CY2018 Q2	100.0	53.0			
CY2018 Q3	96.0	63.0			
CY2018 Q4	95.0	59.0			
CY2019 Q1	93.0	58.5			
CY2019 Q2	88.46	64.0			

Source: BWMC Application, Updated Q4

# **Staff Analysis and Conclusion**

MHCC staff analyzed the ACC-NCDR CathPCI data and concluded that BWMC met the DTB time standard in each quarter, as shown in Table 3. MHCC staff's analysis differs from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, BWMC complied with this standard, with between 88% and 94% of PCI cases meeting the door-to-balloon time standard, as shown in Table 3. MHCC staff's analysis of the ACC-NCDR CathPCI data also confirmed that BWMC did not receive any transfer patients who received primary PCI services.

MHCC staff concludes that BWMC complies with this standard.

Table 3: BWMC Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Time Period

Quarter			Rolling 8-Quarters			
Time Period	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes
2015q1	18	17	94.4%			
2015q2	23	22	95.7%			
2015q3	27	26	96.3%			
2015q4	28	26	92.9%			
2016q1	20	19	95.0%			
2016q2	27	26	96.3%			
2016q3	23	20	87.0%			
2016q4	25	24	96.0%	191	180	94%
2017q1	30	28	93.3%	203	191	94%
2017q2	24	22	91.7%	204	191	94%
2017q3	24	23	95.8%	201	188	94%
2017q4	21	18	85.7%	194	180	93%
2018q1	19	15	78.9%	193	176	91%
2018q2	23	21	91.3%	189	171	90%
2018q3	29	25	86.2%	195	176	90%
2018q4	20	16	80.0%	190	168	88%

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015- CY 2018.

Note: Calculations for each quarter are based on the procedure date.

10.24.17.07D(4)(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to patients with acute myocardial infarction 24 hours per day, seven days per week.

As shown in Table 4a, BWMC provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients as of one week before the due date of the application.

Table 4a: BWMC Cardiac Catheterization Laboratory Staff

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	3	Interventional Cardiologist
Nurse	5.0 (FTE)	C, M
Technician	5.0 (FTE)	S, M, Room Assist

Source: BWMC Application, Q6a

<sup>\*</sup>Scrub (S), circulate (C), monitor (M)

<sup>\*</sup>The CCL also retains 1 Supplemental Staffing Program (SSP) RN

In addition to the staff listed in Table 4a, BWMC also has a CCL Manager and a registered nurse sometimes who fills shifts as needed.

# **Staff Analysis and Conclusion**

MHCC staff compared the staff levels described by BWMC to information reported in BWMC's application for renewal of its waiver for primary PCI services, which was submitted in 2013. MHCC staff also compared the reported staffing levels at BWMC to the programs at three other hospitals with similar case volumes, based on the other hospitals' applications for a Certificate of Ongoing Performance, as shown in Table 4b.

Table 4b: BWMC and Other PCI Programs Cardiac Catheterization Laboratory Staff

Program & Year Reported	Total PCI Volume in Year Prior*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
BWMC 2013	223	N = 4	5.0	5.0
BWMC 2019	315	N = 3	5.0	5.0
Saint Agnes Hospital 2019	465	N = 4	7.2	5.0
Anne Arundel Hospital 2019	447	3.4 FTEs	7.5	6.0
John Hopkins Bayview				
Medical Center 2019	200	N = 10	6.0	5.8

Sources: BWMC 2019 PCI Certificate of Ongoing Performance Application, BWMC 2013 PCI Waiver Application, Saint Agnes Hospital Center 2019 PCI Certificate of Ongoing Performance Application, Anne Arundel Hospital 2019 PCI Certificate of Ongoing Performance Application, Johns Hopkins Bayview Medical Center 2019 PCI Certificate of Ongoing Performance Application

\*Note: The volume reported in 2013 by BWMC was 2011 PCI volume; the volumes for all other hospitals are for CY or FY 2018.

Staffing changes from BWMC's 2013 waiver application to the current application include a decrease from four physicians to three physicians and increases in both the number of nurses and technologists. Although in BWMC's initial application for a Certificate of Ongoing Performance the number of nurse FTEs and technician FTEs was five, BWMC reported that in 2019, staffing was increased from five registered nurses and five technicians to six registered nurses and six technicians. Staffing was again increased in 2020 to add another registered nurse and technician, resulting in a total of 7.0 nursing FTEs and 7.0 technician FTEs. BWMC reported that the hospital currently does not utilize any per diem staff. The staffing levels reported for BWMC are consistent with the level expected given the volume of PCI cases for its program.

MHCC staff concludes that there is adequate nursing and technical staff to provide services; BWMC complies with this standard.

10.24.17.07D(4)(d) The hospital president or Chief Executive Officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.

BWMC provided a signed letter of commitment from Karen E. Olscamp, President and Chief Executive Officer, acknowledging that BWMC will provide primary PCI services in accord

with the requirements established by the Commission. In her letter, Ms. Olscamp stated that the hospital fully supports the PCI program.

# **Staff Analysis and Conclusion**

MHCC staff reviewed the letter of commitment provided and concludes that BWMC meets this standard.

10.24.17.07D(4)(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

BWMC reported that the hospital retains one RN Data Coordinator (1 FTE) who is responsible for data management, reporting, and coordination with institutional quality improvement efforts. The Data Coordinator co-leads monthly multi-disciplinary Cardiac Collaborative meetings with an interventional cardiologist. Other staff who are responsible for data management, reporting, and coordination of quality improvement include staff in the Clinical Decision Support Department. These staff compile and presents data for internal meetings and for the medical director of the CCL. Prior to meetings, all data are reviewed by the Director of Accreditation, Manager of Clinical Decision Support, and Manager of the CCL.

# **Staff Analysis and Conclusion**

MHCC staff concludes that BWMC is compliant with this standard.

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

Dr. Ratnakar Mukherjee was appointed as the Medical Director of the CCL at BWMC on December 31, 2017. Prior to Dr. Mukherjee's appointment, Dr. Samuel C. Yoon was the Medical Director of the CCL between October 1, 2009 and December 31, 2017. The Medical Director of the CCL is responsible for oversight of PCI services, quality, and operations. The Medical Director reviews all PCI cases at a weekly case review meeting. The Medical Director also reviews and presents external and peer review summaries and oversees equipment improvements. In addition, the Medical Director collaborates with the multidisciplinary and corporate quality improvement committees, participates in quality improvement projects, and participates in the STEMI on-call schedule.

#### **Staff Analysis and Conclusion**

MHCC staff concludes that BWMC complies with this standard.

10.24.17.07D(4)(g) The hospital shall design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

BWMC provided a list of the continuing educational programs and activities that staff in the cardiac catheterization lab and critical care unit participated in between January 2015 and December 2018. Staff participated in multi-faceted learning sessions including vendor in-services, education fairs, online modules, and hands-on training. All staff are required to take a course in basic life support (BLS) every two years, and all registered nurses are required to take a course in advanced cardiovascular life support (ACLS) every two years. BWMC submitted a list of the specific continuing education activities that are required of staff. Prior to March 2019, there was not a minimum number of hours of continuing education required. However, BWMC reported that beginning in March 2019 staff are required to complete a minimum of ten continuing education hours per year.

# **Staff Analysis and Conclusion**

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that BWMC meets this requirement.

10.24.17.07D(4)(h) The hospital shall have a formal, written agreement with a tertiary care center that provides for the unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCl, for hospitals performing primary PCI without on-site cardiac surgery.

Kathleen McCollum, SVP COO, signed and dated an agreement with University of Maryland LLC, a tertiary care center, for the unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI because BWMC performs primary PCI without on-site general cardiac surgery. The transfer policy states that the UMMC will accept patients provided that the hospital has the appropriate capacity and capability.

# **Staff Analysis and Conclusion**

MHCC staff reviewed the patient transfer agreement and concludes that BWMC meets this standard.

10.24.17.07D(4)(i) A hospital shall maintain its agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

Kathleen McCollum, SVP COO, signed and dated an agreement with Maryland Expresscare, a division of the University of Maryland Medical System. The agreement guarantees the arrival of an air or ground ambulance within 30 minutes of a request for the transport of a primary PCI patient to a tertiary care center.

# **Staff Analysis and Conclusion**

MHCC staff reviewed the agreement submitted by BWMC and it states that Expresscare will provide ground transportation certified by MIEMSS as an ALS ambulance and appropriately configured and equipped to complete critical care/specialty care patient transfers within thirty minutes or less of a request for a patient undergoing cardiac surgery services. The agreement¹ states that Maryland Expresscare will provide vehicle(s) to provide services and that they shall arrive at BWMC within thirty minutes or less of a request for a patient undergoing cardiac surgery services. Per this agreement, ambulances are staffed with a licensed Emergency Medical Technician (EMT)-Basic and an EMT-Paramedic; Expresscare will also provide the appropriate staff for the particular patient being transported (e.g. Cardiac Rescue Technician-Intermediate, EMT-B, EMT-Paramedic, RN).

MHCC staff concludes that BWMC complies with this standard.

# Quality

10.24.17.07D(5)(a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

BWMC provided the dates of interventional care review meetings between January 2015 and December 2018. Additionally, BWMC provided attendance information for January 2019 through February 2020. BWMC reported that the review of each PCI case includes consideration of patient medical history, angiographic images, medical test results, and patient disposition. The physician who performed the PCI case presents the case to peers.

# **Staff Analysis and Conclusion**

BWMC reported that weekly case review meetings include a review of all PCI cases and all patients who are transferred for coronary artery bypass grafting. The Medical Director of the CCL, interventional cardiologists, and other program staff (e.g. CCL nurses and technicians) are present for reviews.

MHCC staff concludes that BWMC complies with this standard.

10.24.17.07D(5)(b) A hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

BWMC has two multiple care area groups. The PCI Multi-care Committee is small group that meets every other month. This committee includes physician and nursing leadership from the

<sup>&</sup>lt;sup>1</sup> For a copy of this agreement refer to the BWMC Application, Q12, Second Amended and Restated Agreement for Interfacility Transport of Both Primary Angioplasty and Non-primary Angioplasty Patients, Exhibit A

CCL, the coronary care unit, and perioperative care unit, along with representatives involved with quality improvement and data analysis. The Cardiac Collaborative Practice Team is a larger group, and it meets every other month with broad representation from the coronary care unit, CCL, and perioperative care unit, as well as representatives from the emergency department, quality improvement, pharmacy, accreditation, rehabilitation, and others. For the period of July 2014 to December 2018, BWMC provided a list of meeting dates and attendees.

# **Staff Analysis and Conclusion**

MHCC staff reviewed the documentation provided and noted that several monthly meetings were cancelled. BWMC explained that in 2018, there were several personnel changes that resulted in cancelled meetings. Due to these changes, some meetings continued, and some meetings were postponed until new personnel were in place. Four meetings were cancelled in 2015; two meetings were cancelled in 2016; four meetings were cancelled in 2017; and three meetings were cancelled in 2018. The hospital should strive to ensure that meetings occur monthly in future years.

MHCC staff recommends that the Commission find that BWMC meets this standard.

10.24.17.07C(4)(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

BWMC submitted copies of its external review reports for the period from January 2015 through June 2019. BWMC uses an MHCC approved review organization, the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), to review medical records and CCL images for elective PCI cases on a semiannual basis. BWMC also reported that the Medical Director reviews and discusses the MACPAQ reports with the other interventionalists.

# **Staff Analysis and Conclusion**

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. Although only 5% of cases are required to be reviewed, beginning in the second half of 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. As shown in Table 5, between 5.8% and 9.3% of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed.

Table 5: Description of BWMC External Review Of Elective PCI Cases by Year

Time Period	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
CY 2015	229	18	7.9%	Semiannual	Yes
CY 2016	194	18	9.3%	Semiannual	Yes
CY 2017	197	17	8.6%	Semiannual	Yes
CY 2018	205	15	7.3%	Semiannual	Yes
2019 Q1Q2	191	11	5.8%	Semiannual	Yes

Source: MACPAQ Reports, MHCC Analysis

For the period between January 2015 and June 2019, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that at least five percent of elective PCI cases were reviewed, and if fewer than three cases were performed by an interventionalist, then all cases were reviewed by MACPAQ, as required.

MHCC staff concludes that BWMC complies with this standard.

# 10.24.17.07C(4)(d) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

- (i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or
- (ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than 3 cases during the relevant period, as provided in Regulation .08; or
- (iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraphs .07C(4)(d)(i).

10.24.17.07D(5)(c) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

(i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or

<sup>\*</sup> Each review during the calendar year contained three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

- (ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or
- (iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).

10.24.17.07D(5)(d) The performance review of an interventionalist referenced in Paragraph .07D(5)(c) shall:

- (i) Include a review of angiographic images, medical test results, and patients' medical records; and
- (ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

In addition to the external peer review process, individual interventionalists are reviewed through BWMC's Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) processes. These two processes are outlined in BWMC's Medical Staff Peer Review Policy. OPPE occurs every six to eight months, and the aspects of care are evaluated, including interpersonal and communication skills, delinquent medical records, utilization data and patient care. Additionally, cases are reviewed during weekly peer review meetings.

# **Staff Analysis and Conclusion**

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists.

The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is greater, per interventionalist, as part of an external review meets the standard, and

the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).

In addition to the external review, BWMC performs weekly peer review of PCI cases that includes a review of patient history, presentation of symptoms, images from medical tests, other medical test results, and patient disposition. The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records.

MHCC staff validated that the minimum number of cases were included in the external review through analysis of the ACC-NCDR CathPCI data submitted for the period January 2015 through December 2018. In almost all review cycles, the minimum number of cases reviewed was 10% or less of the volume of PCI cases performed by the interventionalists. However, by reviewing an additional four cases internally each year for each interventionalist, the case review requirement for an individual interventionalist would be met. The information provided by BWMC indicates that the standard is met through a combination of external and internal review.

MHCC staff concludes that BWMC satisfactorily conducts individual interventionalist review as stated in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).<sup>3</sup>

10.24.17.07D(5)(e) The chief executive officer of the hospital shall certify annually to the Commission that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in this chapter, including those regarding internal peer review of cases and external review of cases.

BWMC submitted an affidavit from the Karen E. Olscamp, Chief Executive Officer, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

# **Staff Analysis and Conclusion**

MHCC staff concludes that BWMC complies with this standard.

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review cases.

<sup>2</sup>https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\_cardiaccare/documents/con\_cardiac\_csac\_bulletin\_pci\_cases\_20151020.pdf

<sup>&</sup>lt;sup>3</sup> Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.

- (i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.
- (ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.
- (iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

BWMC submitted a list of quality improvement activities during the period between January 2015 and December 2018. Examples of quality improvement topics mentioned by BWMC are heparin dosing review, addition of contrast enhanced echocardiograms, and cardiac rehabilitation and capacity expansion. BWMC also submitted meeting minutes from the PCI Multi-care Committee and Cardiac Collaborative between August 2014 and December 2018.

# **Staff Analysis and Conclusion**

MHCC staff reviewed meeting minutes and descriptions of quality assurance activities and concludes that BWMC complies with this standard.

# **Patient Outcome Measures**

10.24.17.07C(5)(a) An elective PCI program shall meet all performance standards established in statute or in State regulations.

- (b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.
- (c) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for primary PCI cases.

10.24.17.07D(5)(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

- (b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.
- (c) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for primary PCI cases.

BWMC submitted adjusted mortality by rolling 12-month reporting period for 2015 Q1 through 2019 Q2 when available, as shown in Table 6. These data are not available for any hospitals participating in the ACC-NCDR CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

Table 6: BWMC Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

	STEMI			NONSTEMI				
Reporting Period	Hospital AMR	95% CI	National AMR	Meets MHCC Standard	Hospital AMR	95% CI	National AMR	Meets MHCC Standard
2018q3-2019q2	4.95	[1.36, 12.30]	6.38	Yes	NR	[0.00, 1.54]	1.00	Yes
2018q2-2019q1	5.05	[1.05, 14.35]	6.13	Yes	NR	[0.00, 2.3]	0.99	Yes
2018q1-2018q4	4.70	[0.57, 16.49]	6.00	Yes	0.58	[0.01, 3.19]	1.00	Yes
2017q4-2018q3	2.42	[0.06, 13.16]	6.54	Yes	0.40	[0.01, 2.20]	0.98	Yes
2017q3-2018q2	No	ot available for a	ny hospitals	participating	in the ACC-	NCDR CathPC	l Data Regis	try
2017q2-2018q1	3.17	[0.39, 11.08]	6.91	Yes	0.66	[0.02, 3.64]	1.03	Yes
2017q1-2017q4	3.88	[0.81, 11.02]	6.86	Yes	0.62	[0.02, 3.41]	0.99	Yes
2016q4-2017q3	3.04	[0.37, 10.71]	6.75	Yes	0.94	[0.02, 5.20]	0.98	Yes
2016q3-2017q2	7.70	[3.14, 15.28]	6.64	Yes	1.58	[0.19, 5.64]	0.95	Yes
2016q2-2017q3	7.94	[2.96, 16.68]	6.77	Yes	1.55	[0.19, 5.52]	0.97	Yes
2016q1-2017q4	8.79	[3.60, 17.35]	6.82	Yes	0.95	[0.11. 3.37]	0.95	Yes
2015q4-2016q3	9.26	[3.80, 18.27]	6.71	Yes	0.99	[0.12, 3.53]	0.95	Yes
2015q3-2016q2	5.58	[1.54, 13.80]	6.66	Yes	0.51	[0.01, 2.80]	0.93	Yes
2015q2-2016q1	5.50	[1.52, 13.58]	6.45	Yes	0.56	[0.01, 3.08]	0.90	Yes
2015q1-2015q4	3.79	[0.46, 13.28]	6.26	Yes	1.28	[0.03, 7.08]	0.90	Yes

Source: MHCC Staff compilation of results from the hospital's quarterly reports form the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between January 2015 and June 2019.

Notes: NR" means not reported. When a hospital has zero deaths for a reporting period, the hospital's AMR is labeled NR. A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the National AMR or indicates statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or Non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable.

# **Staff Analysis and Conclusion**

This standard is not applicable for the majority of the review period for BWMC's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark, and MHCC staff were not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. However, MHCC staff has provided information below on how BWMC performed over the period between January 2015 and June 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and NONSTEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for BWMC for all 12-month reporting periods between 2015 Q1 and 2019 Q2, when an adjusted mortality rate was reported. For the NSTEMI patients, BWMC had no deaths for the two most recent reporting periods shown in Table 6. When a hospital has no deaths during a reporting period, then no adjusted mortality rate is reported. MHCC staff concludes that BWMC would have met this standard, if it was applicable for the period reviewed. A report for the hospital's performance for the period ending December 2019, will be the first period for which the current standard applies.

#### **Physician Resources**

10.24.17.07D(7)(a)Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24 month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Maryland Health Care Commission on a quarterly basis.

BWMC submitted information on the volume of primary and elective PCI cases at BWMC and other hospitals, by physician and quarter, for the period from July 2014 through December 2018. This detailed information was provided for the following four physicians: Dr. Ratnakar Mukherjee, Dr. Kelly Miller, Dr. A. Gupta, and Dr. Samuel Yoon. Drs. Mukherjee, Miller, and Gupta signed and dated affidavits affirming under penalties of perjury that the PCI volume information is true and correct to the best of their knowledge. In the case of Dr. Samuel Yoon, the previous Medical Director of the CCL who left employment in early 2018, Dr. Ratnakar Mukherjee, the current Medical Director, signed and dated an affidavit.

#### **Staff Analysis and Conclusion**

MHCC staff reviewed reported physician volume for the three current interventionalists, at the time of application submission, and the interventionalists who previously provided PCI services as BWMC. Staff determined that all of these interventionalists performed at least 50 PCI procedures on average over each of two 24-month periods.

BWMC complies with this standard.

10.24.17.07D(7)(b)Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

BWMC responded that this regulation is not applicable.

#### **Staff Analysis and Conclusion**

MHCC staff determined that this standard does not apply to BWMC. While BWMC lacks on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually on average over a 24 month period.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24 month period, who took a leave of absence of less than one year during the 24 month period measured, may resume the provision of primary PCI provided that:

- (i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;
- (ii) The physician continues to satisfy the hospital's credentialing requirements; and
- (iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.

BWMC responded that this regulation is not applicable.

# **Staff Analysis and Conclusion**

MHCC staff determined that this standard does not apply to BWMC. While BWMC lacks on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually on average over each of two 24-month periods.

10.24.17.07D(7)(e) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or completed their training before 1998 and did not seek board certification before 2003 [or physicians who completed a fellowship in interventional cardiology less than three years ago].

10.24.17.07D(7)(f)Each physician shall obtain board certification within three years of completion of a fellowship in interventional cardiology.

BWMC submitted a signed and dated statement from Dr. Ratnakar Mukherjee, Medical Director of CCL, acknowledging that all physicians performing primary PCI services at BWMC (i.e. Dr. Ratnakar Mukherjee, Dr. Kelly Miller, and Dr. Anuj Gupta) are board certified in interventional cardiology.

#### **Staff Analysis and Conclusion**

MHCC staff reviewed the letter provided and concludes that BWMC meets these standards.

10.24.17.07D (7)(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology during every two years of practice.

BWMC submitted signed and dated attestations from Dr. Ratnakar Mukherjee, Dr. Anuj Gupta, and Dr. Kelly Miller stating each physician completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

# **Staff Analysis and Conclusion**

MHCC reviewed the statements provided and concludes that BWMC meets this standard.

10.24.17.07D (7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

BWMC submitted a signed statement from the Medical Director of the CCL, Dr. Ratnakar Mukherjee, acknowledging that each physician who has performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. BWMC also submitted a copy of the on-call schedule for March 2019.

#### **Staff Analysis and Conclusion**

Staff examined the on-call schedule for March 2019 and observed that Drs. Mukherjee, Miller, and Gupta were all scheduled to be on-call at different times during the month.

MHCC staff concludes that BWMC meets this standard.

#### **Volume**

- 10.24.17.07C(7)(a) The target volume for an existing program with both primary and non-primary PCI services is 200 cases annually.
  - (b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subject to a focused review.

BWMC provided the number of primary PCI, elective PCI, and total case volume by quarter between July 2014 and December 2019, as shown in Table 7.

#### **Staff Analysis and Conclusion**

MHCC staff reviewed the table submitted by BWMC. Between July 2014 and December 2019, the CCL had a total of between 65 and 93 cases per quarter. Staff determined at least 200 PCI procedures were completed per year during this time period, as shown in Table 7.

Table 7: BWMC PCI Volume, CY 2015- CY 2019

Calendar Year	Primary PCI	Elective PCI	Total PCI
2015	104	227	331
2016	99	223	322
2017	101	198	299
2018	120	195	315
2019	163	219	382

Source: BWMC Application, Updated Q28

BWMC complies with this standard.

10.24.17.07D(8)(a) For primary PCI cases, if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers, a focused review will be triggered.

BWMC responded that this regulation is not applicable. As shown in Table 7, BWMC also provided the primary PCI volume by calendar year to demonstrate that the primary PCI volume exceeded the threshold in the standard for triggering a focused review.

# **Staff Analysis and Conclusion**

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2018. This analysis is consistent with the volume reported by BWMC, and it confirms that BWMC exceeded the threshold of 49 cases annually referenced in the standard.

MHCC staff determined that this standard does not apply to BWMC.

10.24.17.07D(8)(b) The target volume for primary PCI operators is 11 or more primary cases annually.

BWMC provided the number of primary PCI cases by interventionalist from September 2014 to December 2018.

#### **Staff Analysis and Conclusion**

MHCC staff reviewed the information submitted by BWMC, and it shows that between July 2014 and December 2018, at least 11 primary PCI procedures were completed per year for each interventionalist. Staff also analyzed the data in the ACC-NCDR CathPCI registry for CY

2015- CY 2018 and concluded that each interventionalist met the target of 11 or more primary PCI cases annually.

MHCC staff concludes that BWMC meets this standard.

# **Patient Selection**

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

- (a) Patients described as appropriate elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.
- (b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, are not suitable for elective PCI.

BWMC stated that it reviewed all cases in the ACC-NCDR CathPCI Registry reports included in the PCI Appropriate Use Criteria (AUC) Metric for the period of January 2013 through June 2018. BWMC concluded that all cases met Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines.

BWMC also stated that the external review process did not identify any patients who received elective PCI services inappropriately. Over the review period, the ACC-NCDR's CathPCI registry reports, for one metric, categorized one PCI case as rarely appropriate. Upon further review of the medical record, BWMC determined that the patient had been started on an antianginal beta blocker prior to undergoing elective PCI, but this was not included in the patient records for the ACC-NCDR CathPCI registry. BWMC also stated that according to the ACC 2017 Appropriate Use Criteria for Coronary Revascularization in Patients with Stable Ischemic Heath Disease, this patient would then be categorized as "May Be Appropriate."

# **Staff Analysis and Conclusion**

MHCC staff reviewed external review reports from 2015 through June 2019 and determined that there were no cases between January 2019 and June 2019 that were determined to be "rarely appropriate" with respect to clinical criteria, angiographic criteria, or ACC/AHA appropriateness criteria.

MHCC staff concludes that BWMC complies with the standard.

10.24.17.07D(9) A hospital shall commit to providing primary PCI services only for suitable patients. Suitable patients are:

- (a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.
- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.
- (c)Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.
- (d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient.

BWMC stated that all cases in the ACC-NCDR CathPCI Registry that were labeled as not meeting Appropriate Use Criteria (AUC) in reports from CY 2013-2018 Q2 were reviewed. BWMC determined that all the cases were appropriate based on the ACCF/AHA/SCAI Guidelines. BWMC also reported that no PCI patients received thrombolytic therapy that subsequently failed during the review period.

# **Staff Analysis and Conclusions**

MHCC staff concludes that BWMC complies with the standard.

#### RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff concludes that BWMC meets all of the requirements for a Certificate of Ongoing Performance. The Executive Director of Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits BWMC to continue providing primary and elective percutaneous coronary intervention services for four years.